REMARKS

Reconsideration is requested.

Claims 17-20, 23-26, 31 and 33-35 are pending.

The Section 112, first paragraph "written description", rejection of claims 17-20, 23-26, 31 and 33-35 is traversed. Reconsideration and withdrawal of the rejection are requested in view of the remarks and evidence of record as well as the following remarks and the attached.

One of ordinary skill in the art will appreciate from a review of the specification that the applicants were in possession of the claimed invention at the time the application was filed. The specification describes anti-PTHrP (34-53) antibodies, as required by the claimed invention.

The present specification describes, for example, that the antibodies used as exemplified embodiments of the claimed invention bind to an intermediate region of PTHrP which targets amino acids 34-53[1]. Contrary to the Examiner's assertion[2], one of ordinary skill will appreciate that the exemplified antibody Ab-2 (Oncogene) binds to amino acids 34-53 of PTHrP.[3]

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[1] See for example, page 27, line 1 of the specification ("Int. region: anti-PTHrP (34-53) antibody (Ab-2, Oncogene) 2 µg/ml); ¶8. of the Rule 132 DECLARATION of Dr. OULAD ABDELGHANI executed November 27, 2008 (of record); as compared to the Examiner's suggestion that that the antibodies of the examples bind to an intermediate region of amino acids 36-53 ("in the examples the antibodies used for the amino terminal is 1-34, the intermediate is 36-53, and the carboxy terminal is 107-139 (pages 26-27)." see page 4, lines 2-3 of the Office Action dated February 23, 2009).

[2] "While one would understand that the antibody from Oncogene binds to an epitope within residues 36-53, there is no disclosure of residues 34-53, except provided in the name of the Oncogene antibody." See page 4, lines 9-11 of the Office Action dated February 23, 2009.

[3] See for example, ¶¶8., 15. and 17.-23. of the Rule 132 DECLARATION of Dr. OULAD ABDELGHANI executed November 27, 2008 (of record), and the passages of the specification referred to therein.

One of ordinary skill in the art will appreciate from the present specification as well as from the generally advanced level of skill in the art that the exemplified antibody Ab-2 (Oncogene) binds to amino acids 34-53 of PTHrP.[4] The PTHrP-targeted region of the claims is described generally and through an exemplified embodiment in the present specification.

The Examiner has again referred to In re Smith 173 USPQ 679 (CCPA 1972) in support of the rejection.[5] The applicants have provided a detailed analysis of the holding of Smith as the applicants believe the decision applies to the facts of the present application.[6] The Examiner's reliance on In re Smith is misplaced for the reasons of record.

Consideration of the following further remarks is requested.

As explained in Capon v. Eshhar, 76 USPQ.2d 1078, 1084 (Fed. Cir. 2005),

> The "written description" requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed. *See Enzo Biochem*, 296 F.3d at 1330 (the written description requirement "is the quid pro quo of the patent system; the public must receive meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time"); *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345-46 (Fed. Cir. 2000) (the purpose of the written description requirement "is to ensure that the scope of the right to exclude . . . does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification"); *In re Barker*, 559 F.2d 588, 592 n.4 (C.C.P.A. 1977)

[4] See for example, ¶¶4.-8. of the Rule 132 DECLARATION of Dr. OULAD ABDELGHANI executed November 27, 2008 (of record), and the passages of the specification and references referred to therein.

[5] See page 4 of the Office Action dated February 23, 2009.

[6] See pages 8-17 of the Amendment filed November 27, 2008.

> (the goal of the written description requirement is "to clearly convey the information that an applicant has invented the subject matter which is claimed"). The written description requirement thus satisfies the policy premises of the law, whereby the inventor's technical/scientific advance is added to the body of knowledge, as consideration for the grant of patent exclusivity.
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> The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science. Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.

Further, the Court of Appeals for the Federal Circuit has explained as follows in In re Kenneth Alonso (2008-1079 Fed. Cir. October 30, 2008)[7] with regard to the written description requirement in the case of a criteria for a claim defining a genus of antibodies.

> The written description requirement of 35 U.S.C. § 112, ¶ 1, is straightforward: "The specification shall contain a written description of the invention … ." To satisfy this requirement, the specification must describe the invention in sufficient detail so "that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought.
>
> The requirement "serves a teaching function, as a 'quid pro quo' in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time."
>
> The requirement is rigorous, but not exhaustive: "[I]t is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that

[7] http://caselaw.lp.findlaw.com/data2/circs/fed/081079p.pdf (April 7, 2009), page 5 (citations omitted).

> the inventor possessed the invention. LizardTech, 424 F.3d at 1345.

The applicants submit that the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter.[8] For example, it is unnecessary for the specification to provide a description of proteins which are already known in the prior art.[9].

In Enzo Biochem v. Gen-Probe, Inc., 63 USPQ2d 1609, 1613 (Fed. Cir. 2002), the court stated that the written description requirement would be met for all of the claims of the patent at issue if the functional characteristic of the claimed invention was coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed.

Finally, the applicants note that the Federal Circuit has stated that as long as an applicant has disclosed a "fully characterized antigen," either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen.[10]

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[8] See Capon 76 USPQ.2d 1085.
[9] See Capon 76 USPQ.2d 1087.
[10] See Noelle v. Lederman, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004)

In the present application, the polypeptide sequence of PTHrP is known and fully characterized[11] and the specification teaches that antibodies can be made to fragments of the PTHrP polypeptide[12]. As noted previously, antibodies that bound to known PTHrP fragments (e.g., the fragment spanning amino acid residues 34-53) were known in the art and commercially available[13], demonstrating that both the antigen and antibodies that bound thereto were fully characterized by structure and formula.

The applicants have demonstrated the efficiency of anti-PTHrP (34-53) antibodies in the treatment of kidney cancer by using in the example the anti-PTHrP (34-53) antibody of Oncogene. However, the teaching is not limited to this specific antibody. One of ordinary skill in the art deduces for these results that any anti-PTHrP (34-53) antibody will have the same therapeutic effect. The applicants have provided a Declaration of Dr. Thierry MASSFELDER executed February 14, 2008 (of record) with results obtained with two other anti-PTHrP (34-53) antibodies prepared by the applicants and having the therapeutic effect.

In addition, the specification teaches how to make and use anti-PTHrP (34-53) antibodies, as claimed, as previously acknowledged by the Examiner.[14]

The specification teaches the use of an anti-PTHrP antibody. The PTHrP targeted-region 34-53 only contains 20 amino acids. Therefore, it is a well-defined antigen.[15] Accordingly, the antibodies would have been expected to not vary

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[11] See for example, page 9, lines 22-28 of the present specification.
[12] See page 9, lines 29-33 of the present specification, for example.
[13] See attached additional Calbiochem product sheet as well as the references cited therein.
[14] See for example, pages 9-10 of the Amendment filed November 27, 2008.
[15] The following examples of the antigen is provided for the Examiner's convenience:

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Homo sapiens (human) (NP_945316.1*)              34 AEIRATSEVSPNSKPSPNTK 53
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substantially within the subgenus of the claims. The exemplified anti-PTHrP (34-53) antibody Ab-2 (Oncogene) is sufficiently representative of the subgenus.

As explained by the Federal Circuit in In re Kenneth Alonso[16]

> A genus can be described by disclosing: (1) a representative number of species in that genus; or (2) its "relevant identifying characteristics," such as "complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In the present specification, the amino acids bound by the antibody are disclosed: region 34-53 of PTHrP. The structure of the antigen, and hence the antibody of the claims, is reasonably predictable.

The Declaration Dr. Thierry MASSFELDER executed February 14, 2008 (of record) demonstrates the predictability of the subgenus of the claims as well as the insubstantially variation.

The applicants respectfully submit that the claims are supported by an adequate written description. One of ordinary skill in the art will appreciate that the applicants were in possession of the claimed invention at the time the application was filed. Withdrawal of the Section 112, first paragraph "written description", rejection is requested.

Pan troglodytes (chimpanzee) (XP_001142021.1**)	34	AEIRATSEVSPNSKPSPNTK	53
Canis familiaris (dog) (NP_001003303.1*)	34	AEIRATSEVSPNSKPAPNTK	53
Bos taurus (cow) (NP_777178.1*)	34	AEIRATSEVSPNSKPAPNTK	53
Mus musculus (mouse) (NP_032996.1*)	34	AEIRATSEVSPNSKPAPNTK	53
Rattus norvegicus (rat) (NP_036768.1*)	34	AEIRATSEVSPNSKPAPNTK	53

* http://sib.uniprot.org/

** http://www.ebi.ac.uk/

[16] http://caselaw.lp.findlaw.com/data2/circs/fed/081079p.pdf (April 7, 2009), page 6 (citations omitted).

The claims are submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: /B. J. Sadoff/
B. J. Sadoff
Reg. No. 36,663

BJS:
901 North Glebe Road, 11th Floor
Arlington, VA 22203-1808
Telephone: (703) 816-4000
Facsimile: (703) 816-4100